

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE BIOGEN '755 PATENT
LITIGATION**

**Civil Action No.: 10-2734 (CCC)(JBC)
(consolidated)**

OPINION

CECCHI, District Judge.

Before the Court is EMD Serono, Inc. and Pfizer Inc.'s ("Serono") motion for partial summary judgment as to Biogen MA, Inc.'s ("Biogen") claim of lost profits. ECF No. 271. Bayer Healthcare Pharmaceuticals Inc. ("Bayer") filed a response to Serono's motion. ECF No. 275. Biogen opposes Serono's motion. ECF Nos. 277, 292. The parties also submitted letters to the Court pertaining to Serono's motion. ECF Nos. 297, 461, 467, 472, 739, 753. Having considered the parties' written submissions and oral presentations, for the reasons discussed below the Court denies Serono's motion.

I. FACTUAL AND PROCEDURAL BACKGROUND

In this consolidated patent infringement action, Biogen MA, Inc. ("Biogen") has asserted claims from U.S. Patent No. 7,588,755 (the "'755 patent") against Bayer, Serono, and Novartis Pharmaceuticals Corp. ("Novartis"). The '755 patent claims a method for immunomodulation, or treating viral diseases, cancers, or tumors, by administering to a patient a recombinant polypeptide—human interferon beta ("interferon- β ")—that is produced by a non-human host transformed by a recombinant DNA molecule.

Biogen makes and sells Avonex[®], a recombinant interferon- β product for the treatment of multiple sclerosis ("MS"). Serono makes and sells a competitor recombinant interferon- β product Rebif[®] for the treatment of MS. Rebif[®] has been on the market in the United States since 2002. Serono's Statement of Material Facts Not in Dispute, ECF No. 272-10 ("Serono SOF") ¶ 3.¹ By 2009, when the '755 patent issued, Rebif[®] was generating revenue of approximately \$1 billion per year. *Id.*

In October of 2000, Serono and Biogen entered into a Nonsuit and Option Agreement giving Serono certain rights, including an option to obtain a license to the patent application that later issued as the '755 patent. Serono SOF ¶ 1; ECF No. 272-1. Serono's option to obtain a license to the '755 patent was available to Serono when the '755 patent issued in September of 2009. Serono SOF ¶ 2. To date, Serono has not exercised its option, and the option remains available. *Id.* The Nonsuit and Option Agreement also contains a [REDACTED]

[REDACTED]
[REDACTED] ECF No. 277, at 8.

On May 27, 2010, Bayer filed suit against Biogen seeking a declaration that Bayer does not infringe the '755 patent claims and that the '755 patent claims are invalid. ECF No. 1. On May 28, 2010, Biogen initiated a separate proceeding by filing suit against Bayer, Serono, and Novartis. C.A. No. 10-2760, ECF No. 1. Biogen's infringement claims against Bayer and Novartis are based on the sale of interferon- β products Betaseron[®] and Extavia[®] in the United

¹ Local Civil Rule 56.1 requires a party moving for summary judgment to file a statement of material facts not in dispute. An opposing party must file a responsive statement, addressing each material fact and "indicating agreement or disagreement and, if not agreed, stating each material fact in dispute and citing to the affidavits and other documents." L. Civ. R. 56.1. Any material fact not disputed "shall be deemed undisputed" for purposes of deciding the motion. *Id.*

States for the treatment of MS via immunomodulation. C.A. No. 10-2760, ECF No. 1 at ¶¶ 50-73, ECF No. 61 at ¶¶ 60-83. Biogen's infringement claims against Serono are based on the sale of Rebif® in the United States for the treatment of MS via immunomodulation. C.A. No. 10-2760, ECF No. 1 at ¶¶ 32-49, ECF No. 61 at ¶¶ 42-59. Biogen seeks relief from Serono, Bayer, and Novartis under several remedies, including lost profits. C.A. No. 10-2760, ECF No. 61 at 20.

During the pendency of this case, Serono and Biogen arbitrated whether the Nonsuit and Option Agreement was invalid, unenforceable, terminated, and void. On February 2, 2012, the arbitral tribunal ruled that the agreement is valid and enforceable, and that Serono's option to obtain a license remains in effect. ECF No. 272-2 ¶ 56. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]. In September of 2012, the Court confirmed the tribunal's award. ECF No. 210.

On October 27, 2017, the Court granted Bayer's and Serono's motions for severance. ECF No. 743. With respect to Biogen's action against Serono, a jury trial is scheduled to begin on January 18, 2018. *Id.*

II. LEGAL STANDARDS

A. Summary Judgment

Summary judgment is appropriate if the "depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials" demonstrate that there is no genuine issue as to any material fact, and, construing all

facts and inferences in a light most favorable to the non-moving party, “the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a), (c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The party moving for summary judgment bears the burden of demonstrating the absence of a genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). A fact is “material” if a dispute about that fact “might affect the outcome of the suit under the governing [substantive] law,” and a “genuine” issue exists as to that fact “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. The Court’s role is to determine whether there is a genuine issue for trial, not to weigh the evidence and decide the truth of the matter. *Id.* at 249.

B. Lost Profits

A patent owner, upon a finding that a patent is infringed, is entitled to recover “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty.” 35 U.S.C. § 284. Having prevailed on liability, a patent owner may receive a reasonable royalty or lost profits. *Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d 1352, 1362 (Fed. Cir. 2017). “To recover lost profits, a patent owner must prove a causal relation between the infringement and its loss of profits.” *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1240 (Fed. Cir. 2017) (internal quotation marks and citation omitted). In other words, the patent owner must show a reasonable probability that, “but for” the infringing activity, it would have made the additional profits enjoyed by the infringer. *Micro Chemical, Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017) (“[T]he fact finder’s job is to determine what would the patent holder have made (what would his profits have been) if the infringer had not infringed.”), *reh’g en banc denied*, 870 F.3d 1298 (Fed. Cir. 2017).

There is “no particular required method to prove but for causation” in patent cases. *Mentor Graphics*, 851 F.3d at 1284. One “useful, but non-exclusive” method to establish the patent owner’s entitlement to lost profits is the test first articulated in *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). *Id.* (citation omitted). The *Panduit* test requires the patent owner to show: (1) demand for the patented product; (2) absence of acceptable non-infringing alternatives; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit it would have made. *Id.* at 1285 (citing *Panduit*, 575 F.2d at 1156). Once the patent owner makes a prima facie showing under *Panduit*, it can be reasonably inferred that the lost profits claimed were caused by the infringing sales, and the burden shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales. *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc).

The Federal Circuit has instructed that the “but for” inquiry “requires a reconstruction of the market, as it would have developed absent the infringing product, to determine what the patentee ‘would . . . have made.’” *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (citation omitted). The Federal Circuit further explained that:

Reconstructing the market, by definition a hypothetical enterprise, requires the patentee to project economic results that did not occur. To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture. Within this framework, trial courts, with this court’s approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the “but for world,” and accordingly to recover lost profits in a wide variety of forms. In sum, courts have given patentees significant latitude to prove and recover lost profits for a wide variety of foreseeable economic effects of the infringement.

By the same token, a fair and accurate reconstruction of the “but for” market also must take into account, where relevant, *alternative actions* the infringer *foreseeably would have undertaken* had he not

infringed. Without the infringing product, a rational would-be infringer is likely to offer an acceptable noninfringing alternative, if available, to compete with the patent owner rather than leave the market altogether. The competitor in the “but for” marketplace is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner Thus, an accurate reconstruction of the hypothetical “but for” market takes into account any alternatives available to the infringer.

Id. at 1350-51 (citations omitted) (emphasis added).

“The goal of lost profit damages is to place the patentee in the same position it would have occupied had there been no infringement.” *Mentor Graphics*, 851 F.3d at 1285. The question of legal compensability is one “to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.” *Altana Pharma AG v. Teva Pharms. USA, Inc.*, No. 04-2355, 2013 WL 12157873, at *6 (D.N.J. Jan. 11, 2013) (quoting *Rite-Hite*, 56 F.3d at 1546). While the availability of lost profits presents a question of law, *Rite-Hite*, 56 F.3d at 1544, whether acceptable non-infringing alternatives exist, which may reduce or preclude a lost-profits damages award, presents a question of fact, *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1577 (Fed. Cir. 1992) (citing *Radio Steel & Mfg. Co. v. MTD Prod., Inc.*, 788 F.2d 1554, 1556 (Fed. Cir. 1986)).

III. DISCUSSION

Serono contends that Biogen is precluded from recovering lost profits against Serono as a matter of law. The question Serono asks the Court to decide, and the answer to which Serono contends is indisputably yes, is: In a hypothetical world, did Serono have any alternative by which it could continue competing in the market without infringement? ECF No. 272-9 at 8, 11. Serono argues that its ability to have taken a license to the '755 patent pursuant to the Nonsuit and Option Agreement, and to sell Rebif[®] under license from Biogen, constitutes a non-infringing alternative. Relying on *Grain Processing*, Serono argues that the presence of this non-infringing alternative—

which would have allowed Serono to continue competing against Avonex® in the market without infringing—“breaks the chain of causation required for an award of lost profits.” *Id.* at 1. *See also id.* at 12 (“[T]he existence of Serono’s option to sell Rebif® under license means there are *no circumstances* under which Biogen would have made Serono’s sales in the absence of Serono’s alleged infringement.”) (emphasis in original). Serono also relies on *Grain Processing and Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, No. 96-1718, 2002 WL 1801525 (S.D. Ind. July 5, 2002), for the proposition that non-infringing “alternatives” can include alternative *actions*, not just alternative *products*. ECF No. 286 at 5-6. Serono further relies on *Cardiac Pacemakers* to support its argument that an accused infringer’s product sold under license constitutes a non-infringing alternative.² *Id.* at 6; ECF No. 272-9 at 9-10, 13-14.

By contrast, Biogen asserts that Serono’s motion is contrary to the law of lost profits. According to Biogen, Serono seeks the benefits of the bargain without any of the burdens of its contractual obligations (i.e., challenge validity but also reap the benefit of the license with respect to damages), and that Serono’s proposed rule would “encourage gamesmanship by infringers” and “discourage licensing by inventors.” ECF No. 277 at 4-5. Moreover, Biogen argues that an option that has not been exercised is not a non-infringing alternative in the “but for” world used to determine lost profits. ECF No. 753 at 1. Biogen contends that the Federal Circuit in *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 899 F.2d 1171 (Fed. Cir. 1990) rejected the argument that declining an offered license is a shield against lost-profits liability. ECF No. 277 at 3. Biogen also relies on *Oscar Mayer Foods Corp. v. ConAgra, Inc.*, 869 F. Supp. 656

² Bayer agrees with Serono’s position but limits its response “to clarifying the legal framework applicable to the relevant, multi-party market.” ECF No. 275 at 2 n.2. Specifically, Bayer contends that “if Rebif® is a non-infringing alternative, it must be considered in any damages analysis against Bayer.” *Id.* at 7.

(W.D. Wis. 1994), *aff'd*, 45 F.3d 4542 (Fed. Cir. 1994), to support its argument that this principle applies where there is a contractual obligation to grant a license to the defendant, and *GlobespanVirata, Inc. v. Texas Instruments, Inc.*, No. 03-2854 (D.N.J.) to support its argument that this principle applies where the defendant has an irrevocable right to obtain a license. *Id.* at 20-22. Moreover, relying on *Pall Corp. v. Micron Separation, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995), Biogen argues that an accused product becomes a non-infringing alternative only *after* it becomes licensed; here, Serono never exercised its option. *Id.* at 24-25.

As an initial matter, the cases Serono cites do not mandate the specific relief Serono requests—namely, a pretrial ruling that, as a matter of law, Biogen is not entitled to *any* lost-profits damages from Serono. The district court in *Grain Processing* conducted a three day bench trial, after which it denied lost profits and instead awarded the patentee a reasonable royalty. 185 F.3d at 1347. The Federal Circuit remanded for a calculation of lost-profits damages, and on remand, the district court again held that the patentee was not entitled to lost profits, which the Federal Circuit affirmed. *Id.* at 1348. In *Cardiac Pacemakers*, the question of lost profits was sent to the jury. In that case, an existing market competitor, Ventritex, had a license to the plaintiff's patent. That license terminated when Ventritex merged with the defendant, St. Jude. At trial, St. Jude argued that in a “but for” world, it would not have merged with Ventritex, the license would not have been terminated, and Ventritex's products would have remained on the market as non-infringing alternatives. 2002 WL 1801525, at *76-77. The court instructed the jury that:

If that merger had not occurred (that is, if the infringement had not occurred), the license would have allowed Ventritex to continue manufacturing and selling its products as an independent company. When reconstructing the market in the absence of the infringement, you may take this possibility into account.

Id. at *76. The jury found that no lost profits had been proven, and the court denied plaintiff's motion for a new trial on the issue of lost profits. *Id.* at *77. The case was appealed on different

issues and, after remand back to the district court for a new trial, St. Jude moved for summary judgment dismissing plaintiff's lost profits claim. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 418 F. Supp. 2d 1021 (S.D. Ind. 2006). Despite defending its jury instruction that a decision not to close on a merger could constitute a non-infringing alternative action available to the defendant, the plaintiff was again permitted to present its claim of lost profits to the jury. *Id.* at 1039. Accordingly, neither *Grain Processing* nor *Cardiac Pacemakers* compel the particular relief Serono seeks.

Nevertheless, at this point Biogen has not convinced the Court that Serono's position is completely foreclosed. For instance, while Biogen cites a number of Federal Circuit cases addressing non-infringing alternative *products*, Biogen has not appeared to have cited a case holding that alternatives beyond products should be excluded from consideration in a lost-profits damages analysis. In fact, Serono's cited cases are contrary to Biogen's argument. *See Grain Processing*, 185 F.3d at 1351 (“[A]n accurate reconstruction of the hypothetical ‘but for’ market takes into account any alternatives available to the infringer.”); *Cardiac Pacemakers*, 418 F. Supp. 2d at 1038 (rejecting plaintiff's argument that “*Grain Processing* and its progeny permit a fact-finder to consider only alternative products that were available to the alleged infringer” and that “the jury may not consider more broadly the alternative actions that the alleged infringer might have taken had it not infringed”).

Moreover, contrary to Biogen's assertions, *Beatrice Foods*, *Oscar Mayer*, and *GlobespanVirata* do not appear to proscribe Serono from raising this argument. Of the three cases, the *GlobespanVirata* decision postdates *Grain Processing* and most directly addresses the particular question here—namely, whether the existence of an option or right to obtain a license is

a non-infringing alternative that can break the chain of causation in the lost-profits analysis.³ Judge Brown denied the plaintiff's motion for partial summary judgment on defendant's lost-profits claim, rejecting the assertion that defendant was not entitled to lost profits as matter of law pursuant to *Grain Processing. GlobespanVirata, Inc. v. Texas Instruments, Inc.*, No. 03-2854, ECF No. 239 (D.N.J. Nov. 7, 2005); ECF No. 279-11 at 4-5. As a result of the ruling, the defendant was allowed to prove lost profits to the jury at trial, in addition to a reasonable royalty as an alternative theory. ECF No. 279-12 at 22-23. Judge Brown did not, however, preclude plaintiff from presenting its argument to the jury that defendant cannot establish but for causation in light of defendant's commitment to license its patents. *Id.* at 23. Thus, this Court finds that Serono's argument that a decision by Serono to exercise its option may constitute a non-infringing alternative may proceed at this juncture.

Nonetheless, genuine issues of material fact prevent the Court from granting Serono's motion. Specifically, the parties dispute whether Serono foreseeably *would* have exercised its option to take a license to the '755 patent. Biogen contends that Serono has not submitted any evidence as to whether Serono would have exercised its option in the "but for" world. ECF No. 277 at 29. In addition, Biogen asserts that [REDACTED]

[REDACTED]

[REDACTED]

³ The Court notes that in *Oscar Mayer* the district court explained that "[i]f defendants' position were upheld a tremendous disincentive would be created for any patent holder to liberally license its invention in a manner similar to that employed by the plaintiff." 869 F. Supp. at 667.

Accordingly, Serono has not shown that it is entitled to summary judgment as a matter of law; rather, the Court finds that Serono's motion raises issues that should be presented to the jury.

IV. CONCLUSION

For the reasons discussed above, the Court denies Serono's motion for partial summary judgment as to Biogen's claim of lost profits. An appropriate Order accompanies this Opinion.

Date: December 22, 2017



HON. CLAIRE C. CECCHI
United States District Judge